

APTIDINE 75- ranitidine hydrochloride tablet
A P J Laboratories Limited

RANITIDINE HYDROCHLORIDE

Acid reducer

In case of overdose, get medical help or contact a Poison Control Center right away.

relieves heartburn associated with acid indigestion and sour stomach

prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages

Allergy alert: Do not use if you are allergic to ranitidine or other acid reducers

adults and children 12 years and over:

to relieve symptoms, swallow 1 tablet with a glass of water

to prevent symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages that cause heartburn

can be used up to twice daily (do not take more than 2 tablets in 24 hours)

children under 12 years: ask a doctor

CELLULOSE, MICROCRYSTALLINE

STARCH, CORN

POVIDONE K30

METHYLPARABEN

MAGNESIUM STEARATE

TALC

SODIUM STARCH GLYCOLATE TYPE A POTATO

SILICON DIOXIDE



APTIDINE 75

ranitidine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46084-031
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RANITIDINE HYDROCHLORIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10YB7)	RANITIDINE	75 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	80 mg
STARCH, CORN (UNII: O8232NY3SJ)	30 mg
POVIDONE K30 (UNII: U725QWY32X)	10 mg
METHYL PARABEN (UNII: A218C7H9T)	3 mg
MAGNESIUM STEARATE (UNII: 70097M6I30)	20 mg
TALC (UNII: 7SEV7J4R1U)	30 mg
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	40 mg
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	1 mg

Product Characteristics

Color	pink	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	75MG
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46084-031-15	120 in 1 BLISTER PACK		
2	NDC:46084-031-14	60 in 1 BLISTER PACK		
3	NDC:46084-031-13	36 in 1 BLISTER PACK		
4	NDC:46084-031-12	12 in 1 BLISTER PACK		
5	NDC:46084-031-11	5 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075132	03/01/2013	

Labeler - A P J Laboratories Limited (677378339)

Registrant - A P J Laboratories Limited (677378339)

Establishment

Name	Address	ID/FEI	Business Operations
A P J Laboratories Limited		677378339	manufacture(46084-031)

Revised: 2/2013

A P J Laboratories Limited